

Remarks

In the Restriction Requirement mailed December 3, 2003, the Examiner required restriction to one of seven groups under 35 U.S.C. § 121. The Examiner also imposed an election of species requirement, whereupon Applicants were requested to elect a single nucleic acid species.

In the Restriction Requirement, the claims were divided by the Examiner into the following seven groups:

- I. Claims 1-11 and 20-21, allegedly drawn to an isolated nucleic acid molecule comprising sequence of SEQ ID NO:1, classified in class 536, subclass 22.1;
- II. Claims 12-18 and 51, allegedly drawn to a nucleic acid molecule capable of detecting a single nucleotide polymorphism selected from table 1 and the kit containing the nucleic acid molecule, classified in class 536, subclass 22.1;
- III. Claim 19, allegedly drawn to a nucleic acid molecule which does not hybridize to a nucleic acid molecule consisting of SEQ ID NO: 1, classified in class 536, subclass 22.1;
- IV. Claims 22-40, allegedly drawn to a method of diagnosing glaucoma in a sample classified in class 435, subclass 6;
- V. Claims 41-43 and 48-49, allegedly drawn to a method of detecting the presence or absence of a SNP sequence variation in a sample containing DNA, classified in class 435, subclass 6;
- VI. Claims 44-47, allegedly drawn to a method for detecting the presence or absence of an optineurin promoter sequence variation in a sample, classified in class 435, subclass 6; and
- VII. Claim 51, allegedly drawn to a kit which comprises amplification primers that amplifies an optineurin promoter SNP sequence.

Applicants respectfully traverse the restriction and election requirements, and provisionally elect the claims of Group IV (claims 22-40) and the sequence of SEQ ID NO: 1.

Applicants submit that the complete examination of the application would be handled most expeditiously by treating all of the pending claims as a single entity. As the Manual of Patent Examining Procedure (M.P.E.P.) § 803 directs, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Applicants respectfully submit that the Examiner has not shown that a search and examination of the entire application would cause a serious burden. Rather, a serious burden would arise if the application were restricted.

Moreover, the Examiner argues that "[i]nventions I-III and VII, and IV-VI are related as product and process of use." Office Action at page 3. Section 806.05(h) of the M.P.E.P. states that "[a] product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process." M.P.E.P. § 806.05(h), page 800-46 (Eighth Edition, revised February 2003). Section 806.05(h) further provides that the burden is on the Examiner to provide an example, but the example need not be documented. *Id.*

Applicants respectfully submit that the Examiner has failed to meet her burden to provide an example to satisfy M.P.E.P. section 806.05(h). For at least these reasons, Applicants respectfully request that the Examiner consider Groups I, II, III, IV, V, VI and VII together.

Applicants further note that Groups IV, V and VI are all classified in class 435, subclass 6. Likewise, Groups I, II and III are all classified in class 536, subclass 22.1. Accordingly, Applicants submit that there would be no undue burden for the Examiner to examine Groups IV, V and VI together, nor would there be an undue burden to examine Groups I, II and III together. In fact, an undue burden would arise if these claims were to

be examined separately. Applicants respectfully request that, at the very least, the Examiner consider Groups IV, V and VI together.

Based on the foregoing, Applicants respectfully submit that the restriction requirement is improper and should be withdrawn. Applicants request that, at least, the Examiner modify the Restriction Requirement to examine the claims of Groups IV, V and VI together. Should the Examiner maintain the restriction, Applicants, as noted above, elect the invention of Group IV (claims 22-40), with traverse.

Election of Species

The Examiner alleges that "[t]hese claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs," and requires an election of "no more than one disclosed nucleic acids." Office Action at page 4. Applicants respectfully traverse this requirement. However, in order to facilitate prosecution, Applicants have provisionally elected the sequence of SEQ ID NO: 1, without prejudice to or disclaimer of any unelected subject matter.

Applicants note that the Examiner has alleged that Groups I, II, III and VII are each "drawn to a different nucleic acid sequence." Office Action at page 3. Applicants respectfully disagree. For example, with respect to Group I, Applicants respectfully point out that SEQ ID NO: 1 is a *Homo sapiens* nucleotide sequence of optineurin promoter. *See, e.g.*, specification at page 8. With respect to Group II, Applicants note that the polymorphisms selected from table 1 are polymorphisms in an optineurin promoter. *See, e.g.*, specification at page 18. To the extent that the Examiner intended for the election of species to require an election of a 'single nucleic acid' corresponding to one of the nucleic acids allegedly defined by Groups I, II, III or IV, Applicants hereby traverse any such requirement.

Applicants also note that claims 24 and 34 refer to SEQ ID NOs: 3 through 463. To the extent that the Examiner intended for the election of species requirement to apply to SEQ ID NOs: 3 through 463, Applicants disagree. As noted above, SEQ ID NO: 1 is a

Homo sapiens nucleotide sequence of optineurin promoter. *See, e.g.*, specification at page 8. Applicants also note that SEQ ID NOs: 3 through 463 are *Homo sapiens* nucleotide sequences of DNA motifs, repeat elements, and putative regulatory regions identified in the human optineurin promoter. *See, e.g.*, specification at page 9. As such, SEQ ID NOs: 3 through 463 correspond to partial subsequences of SEQ ID NO: 1. Accordingly, Applicants submit that SEQ ID NO: 1 and SEQ ID NOs: 3 through 463 should be examined together. Examination of SEQ ID NO: 1 and SEQ ID NOs: 3 through 463 together would pose no undue burden on the Examiner.

Moreover, Applicants traverse the apparent restriction to a single nucleotide sequence. This approach contravenes USPTO policy as stipulated in the Manual of Patent Examining Procedure stating that “to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application.” (MPEP, 8th ed., August 2001, Section 803.04). Applicants submit that no serious burden is created for the Examiner by running a simultaneous computerized search of the disclosed nucleic acids. The single search may be run in conjunction with databases such as those available at <http://www.ncbi.nlm.nih>. Therefore, the search of several nucleotide sequences creates no undue burden on the Examiner, whereas, the restriction to a single nucleotide sequence, by contrast, imposes a serious burden on the Applicants.

Applicants respectfully request that the Examiner consider SEQ ID NO: 1 together with SEQ ID NOs: 3 through 463. Should the Examiner maintain the election of species requirement, however, Applicants request that the election requirement be made final, and elect SEQ ID NO: 1, with traverse.

Applicants' Election

Applicants respectfully request withdrawal of the restriction requirement, and request the examination of claims 1 through 51 together in the present application.

Alternatively, Applicants request that the Examiner at a minimum modify the Restriction Requirement to examine the claims of Groups IV, V and VI together.

Additionally, Applicants respectfully request withdrawal of the sequence election requirement, and request that the Examiner consider SEQ ID NO: 1 together with SEQ ID NOs: 3 through 463.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5512 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink that reads "Rachel L. Adams". The signature is written in a cursive, flowing style.

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